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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER
HAMUD, FOZIA M

ART UNIT	PAPER NUMBER
1647	15

DATE MAILED: 09/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

Office Action Summary

Application No.	Applicant(s)
09/800,198	Vernet et al.
Examiner	**Art Unit**
Fozia Hamud	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Sep 5, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above, claim(s) *5-37, 39, 40, and 42-49* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-4, 38, 41, and 50-54* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment adding new claims 50-54, filed on 05 September 2002 in Paper No: 14 is acknowledged. Thus claims 1-54 are pending.

Election/Restriction

2. Applicant's election of the invention of Group I (claims 1-4, 38, 41 and new claims 50-54) in Paper No. 13, filed on 05 September 20021 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 5-37, 39-40, 42-49, are withdrawn from consideration by the Examiner as they are drawn to non-elected inventions. Claims 1-4 will be searched and examined in so far as they pertain to the polypeptide of SEQ ID No: 8.

Information disclosure statement:

3. The references cited in the Search Report (PTO-1449) submitted by Applicants in Paper Nos: 3 and 10, filed on 09 September 2001 and 26 March 2002, respectively, have not been considered because the copies of the references have not been received. Furthermore, the relevance of the cited database references with respect to the elected invention (i.e the polypeptide of SEQ ID NO:8 and a method of producing said polypeptide by expressing the polynucleotide encoding it) is not clear.

Claim Objections

4. Claims 1-4 are objected to because of the following informalities:

4a. Claims 1-4 are objected to, because they recite non-elected SEQ ID Nos. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 101/112

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5a. Claims 1-4, 38, 41 and 50-54 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 1-4, 38, 41 and 50-54 of the instant invention are directed to isolated polypeptide comprising the amino acid sequence set forth in SEQ ID NO: 8, and a method of producing said polypeptide culturing a host cell expressing the polynucleotide of SEQ ID NO:7. Instant specification discloses a number of polypeptides, designated generically as FCTRX and describes them as being novel polypeptides. The specification refers to the claimed polypeptide of SEQ ID NO:8 as FCTR3b, and discloses that it comprises 2733 amino acid residues with a predicted molecular weight of 30324.3 Daltons, (page 36, line 41 through page 37, lin 27). Instant specification does not provide any information regarding physiologic or functional characteristics of the polypeptide of SEQ ID NO:8 or variants thereof. However, it describes FCTR3 as comprising an extracelluar EGF-like repeats and as having significant homology to DOC4 (tenascin M), (see page 93, lines 3-9). The specification goes on to state that based on the bioactivity for related molecules, FCTR3 may play a role in one or more aspects of tumor cell biology and predicts that antibodies against FCTR3 might

result in anti-tumor/anti-metastatic activity, (see page 93, line 30 through page 94, line 24). Although instant specification discloses this information about FCTR3, it does not indicate whether the claimed FCTR3b and FCTR3 are the same protein, and if not what is their relationship. Neither does the specification disclose whether the claimed polypeptide has any homology to tenascin M, and if so what is the percent homology between the claimed protein and tenascin M. Assuming that the claimed polypeptide shares homology with tenascin M, Applicants do not demonstrate that having an extracelluar EGF-like repeats assures the claimed polypeptide with an activity, and the specification does not disclose any evidence showing that the claimed polypeptide does have a role in tumors. The state of the art is such that functional information can be automatically derived from structural information only to a limited extent, (see Skolnick et al, Nature Biotechnology, Vol.18, No.3, pages 283-287, especially page 286, middle of column 1). Skolnick et al also state that knowledge of the overall structure or domain family is still not enough to confidently assign function to a protein. Therefore, since the specification does not provide an activity for claimed polypeptide, one of ordinary skill in the art would not be able to predict what activity would be possessed by the protein of the instant application, based solely it might have significant homology to tenascin M. Instant specification only provides the nucleic acid sequence of the polynucleotide that encodes the claimed polypeptide and deduced amino acid sequence for the claimed polypeptide of SEQ ID NO:8, and this is not sufficient to enable one of skill in the art to predict the activity or biological significance of the claimed polypeptide.

The specific biological role of the claimed protein can not be ascertained, because the claimed invention is directed to a polypeptide of as yet undetermined function or biological significance. Therefore, unless Applicants demonstrate the physiological significance or the biological role of the instant polypeptide, the claimed invention is not supported by either a specific and substantially asserted utility or a well established utility.

5b. Claims 1-4, 38, 41 and 50-54 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Instant specification only discloses the structure of the nucleic acid molecule of SEQ ID NO:7, and discloses a deduced amino acid sequence for the encoded polypeptide of SEQ ID NO:8, however, it does not disclose an activity for the claimed protein, or any structural features that might enable of ordinary skill in the art to predict an activity for it. Therefore the skilled artisan would not know how to use the polypeptide of SEQ ID NO:8.

Should Applicants establish an activity for the polypeptide of SEQ ID NO: 8, instant specification would still fail to adequately describe and enable a mature form, or a variant which differs no more than 15% from the polypeptide of SEQ ID NO:8 or an allelic variant of SEQ ID NO:8, as claimed in claims 1-4.

Instant specification fails to describe the structure of the "mature form " or "variant of the mature" or an allelic variant or a variant that differs no more than 15% from the polypeptide of SEQ ID NO:8, neither is instant specification enabling for a pharmaceutical composition comprising the

polypeptide of SEQ ID NO:8. Applicants are claiming very specific species which are not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed had possession of the claimed invention. Applicants define "allelic variants" as being FCTRX proteins that might have alterations in "non-essential" amino acid residues, without altering the functional ability of FCTRX, (page 133, lines 1-14). However, Applicants fail to provide those amino acid residues of the disclosed naturally-occurring polypeptide of SEQ ID NO:8, which are required for functional and structural integrity of the claimed polypeptide, and those that can be changed without altering the function of the claimed polypeptide. Therefore, solely based on the amino acid sequence of the polypeptide of SEQ ID NO:8, the skilled artisan can not envision the structure of a "mature", or a variant of a mature, because the protein might be differentially processed depending on which tissue it is expressed in. The claims are directed to species, the structure of which cannot be determined from the deduced amino acid sequence, and instant specification does not provide evidence for the isolation or conception of the structure of a "mature" or a variant of a mature or a variant of the polypeptide of SEQ ID NO:8. Therefore, the specification does not provide an adequate written description of the "mature" or "variant" and thus the claimed invention, to the extent that it reads upon a mature form of SEQ ID NO:8 or a variant form of SEQ ID NO:8, was not described in such a way as to reasonably convey to one skilled in the relevant art that the inventors at the time the application was filed had possession of the claimed invention. With respect to claims 38 and 41, while instant specification discloses the polypeptide of SEQ ID NO:8, it does not disclose a pharmaceutical

composition comprising the polypeptide of SEQ ID NO:8, therefore Applicants have not presented enablement commensurate in scope with claims.

Claim rejections-35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> *(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.*

6a. Claim 1 is rejected under 35 U.S.C *§ 102*(a) as being anticipated by Oohashi et al (1999).

Oohashi et al. teach a polypeptide referred to as "mouse Ten-m/odz" which is described as being a member of a new family of dimeric type II transmembrane protein. The polypeptide disclosed by Oohashi et al shares 98.2% identity to the polypeptide of SEQ ID NO: 8, claimed in the instant claim 1. See attached copy of the comparison of SEQ ID NO:8 claimed in the instant invention and the sequences of the references (SEQUENCE COMPARISON 'A'). Therefore Oohashi et al reference anticipates instant claim 1, because it meets the structural limitation of a polypeptide having no more than 15% to SEQ ID NO:8.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Mondays-Thursdays from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary kunz can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
25 September 2002

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600